



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/398,610	09/17/1999	MICHAEL D. EDGE	10275/137001	1306

26161 7590 01/07/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 01/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/398,610

Applicant(s)

Edge

Examiner

Anne Marie Wehbé

Art Unit

1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Dec 2, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Dec 2, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE:

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____
- Claim(s) objected to: _____
- Claim(s) rejected: 1-8, 10-14, and 16-35
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Art Unit: 1632

Attachment to Advisory Action

Applicant's amendment to claims 1 and 16 and arguments have been considered but do not place the pending claims in condition for allowance. The applicant's arguments regarding the rejection of the pending claims under 35 U.S.C. 103 are based on applicant's assertion that the enzymes present in the fusion proteins taught by Hyttinen are not biologically active, and that there is no reasonable expectation that the fusion protein taught by Rybak et al. would be capable of being secreted at high levels in the milk of a transgenic mammal. In regards to the issue of whether Hyttinen teaches "biologically active" enzyme fusion proteins, the final office action addressed this argument, stating that Hyttinen et al. clearly teaches that the fusion protein comprising the enzyme can contain an inactive enzyme or a biologically less active enzyme (Hyttinen et al., column 2, lines 32-54). While the fusion enzyme of Hyttinen may not demonstrate 100% of the activity of the wild type enzyme, a less active enzyme still equates to a "biologically active" enzyme. The applicant's claims do not recite any specific level of activity, they just recite that the enzyme is in a biologically active form.

In regards to the second argument, the applicant is reminded that although a species election of the species "angiogenin" was made by applicant's in paper no.8, the claims have not been amended in scope to recite the elected species. The applicant is also reminded that this application has been examined based on the elected species of "angiogenin". The applicant's argument regarding the teachings of Rybak rests on the disclosure in Rybak that a fusion protein

Art Unit: 1632

comprising an antibody and angiogenin is only secreted at low levels in tissue culture. The applicant argues that since this fusion protein is not secreted at high levels in tissue culture, the skilled artisan would not expect it to be secreted at high levels in a transgenic mammal. If, as applicants argue, there is no reasonable expectation of secreting high levels of an antibody/angiogenin fusion protein in transgenic milk, then it would appear that applicant's data which demonstrates a high level of expression of an antibody/angiogenin fusion protein in transgenic milk represents an unexpected result. However, the claims as written are not commensurate in scope with applicant's "unexpected results" concerning a fusion protein comprising an antibody and angiogenin. Therefore, applicant's claims remain rejected.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

